FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ERIN HOLMES; SHAWN HOLMES, *Plaintiffs-Appellants,* v. MERCK & CO., INC., *Defendant-Appellee.*	No. 08-16557 D.C. No. 2:04-cv-00608- BES-GWF OPINION

Appeal from the United States District Court
for the District of Nevada
Brian E. Sandoval, District Judge, Presiding

Argued and Submitted December 3, 2009
Resubmitted on April 1, 2011
San Francisco, California

Filed September 25, 2012

Before: Betty B. Fletcher, Sidney R. Thomas, and
N. Randy Smith, Circuit Judges.

Opinion by Judge Thomas

COUNSEL

Eckly M. Keach and Robert E. Murdock, Las Vegas, Nevada, for the appellants.

Denice Barton, Las Vegas, Nevada, and Donald F. Zimmer, San Francisco, California, for the appellees.

OPINION

THOMAS, Circuit Judge:

Erin and Shawn Holmes appeal the district court's grant of summary judgment in favor of Merck & Company in their diversity action alleging wrongful death. They contend that the district court erred in applying the standards of the National Childhood Vaccine Injury Act (Vaccine Act or the Act), 42 U.S.C. § 300aa-22, to their individual claims for damages. We have jurisdiction pursuant to 28 U.S.C. § 1291. We affirm.

I

When Jacob Holmes was one year old, his pediatrician administered M-M-R II,[1] a vaccine manufactured and distributed by Merck, in conformity with the recommendations set by the Centers for Disease Control and Prevention. Within nine days, Jacob began experiencing seizures and developed encephalopathies. He died approximately six months later.[2] Acting on behalf of their son Jacob's estate, Erin and Shawn Holmes petitioned for compensation from a government fund created by the Vaccine Act. They received $250,000 through the program.

[1]M-M-R II, the Measles, Mumps, and Rubella, Virus Vaccine Live, was approved by the Food and Drug Administration ("FDA") in 1978 for distribution in the United States. The vaccine has led to more than a ninety-nine percent decrease in those diseases since its introduction.

[2]The parties disagree about whether the vaccine caused Jacob's death, but causation was not at issue in the district court's summary judgment ruling.

Subsequently, acting in their individual capacity and pursuant to Nevada Revised Statute section 41.085, the Holmes initiated this wrongful death lawsuit in Clark County, Nevada.[3] Their complaint set forth allegations of negligence, strict product liability, negligent design, failure to warn, misrepresentation, express warranty, implied warranty of merchantability, implied warranty of fitness for a particular purpose, and punitive damages. Merck removed the case to the United States District Court for the District of Nevada.

After three years of discovery, Merck filed a motion for summary judgment, arguing, as is relevant here, that the Vaccine Act foreclosed Plaintiffs' lawsuit. The district court only partially agreed, holding that the Act limited Plaintiffs' strict liability and negligence claims to the extent that the claims relied on allegations of design defect and failure to warn. But the district court disagreed with Merck's assertion that the Vaccine Act limited Plaintiffs' other state law claims. The district court therefore granted in part and denied in part Merck's summary judgment motion and requested supplemental briefing on Plaintiffs' claims of misrepresentation, breach of warranty, and punitive damages. Following supplemental briefing on these remaining state law claims, the district court granted Merck summary judgment. Plaintiffs then filed a timely appeal to this court, challenging only the district court's application of Section 22 of the Vaccine Act to their

[3]As is relevant, Nevada's Wrongful Death Statute states:

> When the death of any person, whether or not a minor, is caused by the wrongful act or neglect of another, the heirs of the decedent . . . may each maintain an action for damages against the person who caused the death . . . . The heirs may prove their respective damages in the action . . . and the court or jury may award each person pecuniary damages for the person's grief or sorrow, loss of probable support, companionship, society, comfort and consortium, and damages for pain, suffering or disfigurement of the decedent.

Nev. Rev. Stat. § 41.085(2)-(4).

design defect and failure to warn claims. After oral argument, we deferred submission of the case to await the Supreme Court's decision in *Bruesewitz v. Wyeth*, 562 U.S. ___, 131 S. Ct. 1068 (2011).

We review de novo a district court's decision to grant summary judgment. *See, e.g.*, *Universal Health Servs., Inc. v. Thompson*, 363 F.3d 1013, 1019 (9th Cir. 2004). We also review de novo a district court's interpretation and construction of a federal statute. *Lively v. Wild Oats Mkts., Inc.*, 456 F.3d 933, 938 (9th Cir. 2006).

II

A

The question in this appeal is whether the National Childhood Vaccine Injury Act preempts all or part of the Plaintiffs' claims. The National Childhood Vaccine Injury Act is part of the federal government's larger program of approving, regulating, and promoting vaccines. *See* National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, Tit. III, 100 Stat. 3743, 3756-3784 (codified as amended at 42 U.S.C. § 300aa-1 *et seq.*). The Act arose out of an attempt to balance the need for widespread childhood vaccinations with the need for "optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. Congress passed the law after hearing testimony that, although vaccines inevitably harmed only a very small number of people, litigation arising from these injuries was threatening the stability of the nation's vaccine program. *See* H.R. Rep. No. 99-908, at 4-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345-48. In particular, injured persons complained about the tort law system's uncertain and inequitable recoveries, while vaccine manufacturers testified that the high cost of litigation was causing insurance premiums to rise and reducing the number of manufacturers willing to sell childhood vaccines. *See id.* at 6-7; *see also Bruesewitz*, 131

S. Ct. at 1072-74 (describing impetus behind Vaccine Act's creation).

[1] Congress addressed these concerns by establishing a "no fault" national vaccine injury compensation program through which vaccine-injured persons might quickly and easily obtain damage awards from a "Vaccine Court." *See Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994) (describing compensation system and coining "Vaccine Court" term).

Part II of the Act set forth the parameters of this compensation scheme and instituted a "Vaccine Injury Table" to cover the vaccines and injuries, for which individuals could seek compensation.[4] 42 U.S.C. § 300aa-14. Two provisions within Part II—Section 11 and Section 22—are central to the issues presented in this case.

[2] First, in Section 11, Congress stipulated that any claimant "qualified" to bring a claim in Vaccine Court must do so in advance of bringing a civil suit. 42 U.S.C. § 300aa-

[4]Specifically, a claimant may file a petition for compensation with a specially constituted "Vaccine Court," operating under the United States Court of Federal Claims. 42 U.S.C. §§ 300aa-11, 300aa-12. In almost all circumstances, a special master makes a decision on the claimant's petition within 240 days. § 300aa-12(d)(3). The Court of Federal Claims then reviews any objections to the special master's decision and enters final judgment within 120 days. § 300aa-12(e). This informal adjudication relies on the Act's "Vaccine Injury Table," which describes the side effects associated with each vaccine and provides a timetable as to when those effects should manifest themselves. § 300aa-14(a); 42 C.F.R. § 100.3 (current Vaccine Injury Table). Unlike in tort suits, a claimant whose injuries fall within the Table does not need to show causation or fault; rather the claimant need only show by a preponderance of the evidence that he received a listed vaccine and then suffered certain symptoms within a defined period of time. 42 U.S.C. §§ 300aa-13, 300aa-14. Following the adjudication, a claimant may either accept the court's judgment and forego a traditional tort suit for damages, or reject the judgment and seek tort relief from the vaccine manufacturer. § 300aa-21(a).

11(a)(2)(A).[5] The Act specifies that a qualified claimant is "any person who has sustained a vaccine-related injury" after "receiv[ing] a vaccine set forth in the Vaccine Injury Table." § 300aa-11(b)-(c). If a person is not qualified to file a petition for compensation under the Program, then this subsection's exhaustion requirement does not apply. § 300aa-11(a)(9).

[3] Finally, if the person who sustained the vaccine-related injury is a minor, disabled or deceased, the Act permits that person's parent or legal representative to file for compensation on behalf of the injured person's estate. § 300aa-11(b)(1)(A). A parent or legal representative may not, however, file in Vaccine Court for compensation of his or her own individual damages. *See* § 300aa-15(d)(2) ("Compensation awarded under the Program may not include . . . compensation for other than the health, education, or welfare of *the person who suffered the vaccine-related injury* with respect to which the compensation is paid.") (emphasis added). Thus, although we have never had an occasion to rule on the question, our sister courts have consistently held that Section 11's exhaustion requirement does not apply to a parent's claim for his or her individual injuries. *See, e.g.*, *Moss v. Merck & Co.*, 381 F.3d 501, 505-06 (5th Cir. 2004); *Schafer*, 20 F.3d at 5-7.

Section 22 of the Vaccine Act meanwhile provides vaccine manufacturers "significant tort-liability protections," *Bruesewitz*, 131 S. Ct. at 1074, by eliminating liability for injuries from "unavoidable side effects," 42 U.S.C. § 300aa-

[5]In relevant part, 42 U.S.C. § 300aa-11(a)(2)(A) provides:

> No person may bring a civil action for damages . . . against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . and no such court may award damages . . . for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury or death[.]

22(b)(1); eliminating liability for not providing direct warnings to a claimant, § 300aa-22(c); and imposing a presumption that a manufacturer provided proper directions and warnings if the manufacturer complied with FDA requirements, § 300aa-22(b)(2).[6] In this way, the Act sets up a quid

[6]In relevant part, Section 22 states:

(a) General Rule

> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.
>
> (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—
>
> (A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title [fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine, after its approval, or other criminal or illegal activity relating to the safety and effectiveness of vaccines], or
>
> (B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

pro quo: easier and more certain compensation in exchange for limited remedies within the traditional tort system. *See*, e.g., *Bruesweitz*, 131 S. Ct. at 1080 ("[T]he Act's structural *quid pro quo* leads to the same conclusion: The vaccine manufacturers fund from their sales an informal, efficient compensation program for vaccine injuries; in exchange they avoid costly tort litigation and the occasional disproportionate jury verdict.").

Putting these two provisions together, Plaintiffs argue that, because Section 11 of the Vaccine Act renders them ineligible for compensation through the Vaccine Court, no other part of the Act, and particularly not Section 22's tort-liability limitations, should apply to their claims in state court. We disagree. The exhaustion requirement in Section 11 is only a subsection of Congress's larger statutory scheme to ensure that vaccine manufacturers have an affordable and predictable way of handling injured parties' compensation claims. Though parents are not bound by Section 11's exhaustion requirement, they are not free from the Act's tort liability limitations. Regardless of whether a plaintiff is the vaccine-recipient or the parent of one, Section 22 expressly preempts design-defect claims seeking compensation for injury or death caused by a vaccine's unavoidable side effects. § 300aa-22(b). Section 22 expressly preempts tort suits based "solely" on the manufacturer's failure to provide direct warnings to the injured party. § 300aa-22(c). In reaching these conclusions, we do not suggest that the Act otherwise forecloses a parent's state law claims.

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

B

Preemption law begins with the presumption that Congress does not "intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). State action may nonetheless be "foreclosed by express language in a congressional enactment, by implication from the depth and breadth of a congressional scheme that occupies the legislative field, or by implication because of a conflict with a congressional enactment." *Lorillard Tobacco v. Reilly*, 533 U.S. 525, 541 (2001) (internal citations omitted). Thus, when construing an express preemption clause, a reviewing court must necessarily begin by examining the clause's "plain wording," as this "necessarily contains the best evidence of Congress' pre-emptive intent." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63 (2002). "We must not be guided by a single sentence or member of a sentence, but look to the provisions of the whole law, and to its object and policy." *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 51 (1987); *see also Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995) ("The fact that an express definition of the pre-emptive reach of a statute 'implies'—*i.e.*, supports a reasonable inference—that Congress did not intend to preempt other matters does not mean that the express clause entirely forecloses any possibility of implied pre-emption.").

[4] Congress included several clauses in Section 22 that inform our preemption determination. First, in Section 22(a), the Act establishes a default that traditional state tort remedies remain except in several enumerated instances, including as provided for in subsection (b). 42 U.S.C. § 300aa-22(a) ("Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death."). Subsection (b)(1), in turn, declares that manufacturers shall not be liable for injuries caused by "side effects that were unavoidable even though the vaccine . . . was accompanied by proper directions and warnings." And subsection (b)(2) states that proper directions and warnings will be presumed when the

manufacturer "complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act . . . ." To rebut this presumption, the Act requires a plaintiff to show that the manufacturer had (1) engaged in conduct that would subject it to punitive damages under the Vaccine Act; or (2) failed to exercise due care. § 300aa-22(b)(2)(A)-(B).

Pursuant to subsection (c), manufacturers are generally immunized from liability for failure to warn if they have complied with regulatory requirements and have given the warning to the healthcare professional, the vaccine recipient, or the vaccine recipient's legal representative. § 300aa-22(c); *see also Bruesewitz*, 131 S. Ct. at 1074 n.25 ("[I]mmunity does not apply if the plaintiff establishes by clear and convincing evidence that the manufacturer was negligent, or was guilty of fraud, intentional and wrongful withholding of information, or other unlawful activity."). Finally subsection (e) prohibits any state law that is *more restrictive* than the Vaccine Act. 42 U.S.C. § 300aa-22(e) ("No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.").

[5] The text of these clauses indicates that Congress expressly intended to prohibit states from regulating large aspects of tort suits against vaccine manufacturers. The Third Circuit explained the potential scope of this preemption provision: although "stating that 'no state shall pass laws with the following exceptions' may well be broader than a provision stating 'state law applies with the following exceptions' . . . [,] the breadth of a provision does not alter the import of the underlying language, and here that language conveys a clear intent to override state law civil action claims in particular, defined circumstances." *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 243 (3d Cir. 2009), *aff'd*, 131 S.Ct. at 1068; *see also id.* at 242-43 (comparing language in Section 22 of Vaccine Act to analogous express preemption language in Federal Ciga-

rette Labeling Act and Advertising Act); *see, e.g.*, *Lorillard*, 533 U.S. at 541; *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 662 n.2 (1993).[7]

In its recent decision affirming the Third Circuit's reasoning in *Bruesewitz*, the Supreme Court elaborated:

> The "even though" clause [in Section 22(b)(1)] . . . . delineates the preventative measures that a vaccine manufacturer must have taken for a side-effect to be considered "unavoidable" under the statute. Provided that there was proper manufacture and warning, any remaining side effects, including those resulting from design defects, are deemed to have been unavoidable. State-law design-defect claims are therefore preempted.

131 S. Ct. at 1075.

In *Bruesewitz*, the Supreme Court also discussed the interplay between subsections (b)(2) and (b)(1):

> The structure of the [Vaccine Act] and of vaccine regulation in general reinforces what the text of § 300aa-22(b)(1) suggests. A vaccine's license spells out the manufacturing method that must be followed and the directions and warnings that must accompany the product. Manufacturers ordinarily must

[7]Other courts have reached the similar conclusion that design defect claims are expressly preempted by Section 22. *See, e.g.*, *Abbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1117 (4th Cir. 1988) (Sections 22(b), (c), and (e) "expressly preempt state law in several respects"); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 662-66 (S.D. Tex. 2004) (same). Courts have likewise recognized the Vaccine Act's express limitations on failure to warn claims. *See, e.g.*, *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 295 (E.D. Pa 2007) ("Vaccine Act clearly bars claims based on a vaccine manufacturer's failure to provide warnings to an individual who receives its vaccine.").

> obtain the Food and Drug Administration's (FDA) approval before modifying either. Deviations from the license thus provide objective evidence of manufacturing defects or inadequate warnings. Further objective evidence comes from the FDA's regulations—more than 90 of them—that pervasively regulate the manufacturing process, down to the requirements for plumbing and ventilation systems at each manufacturing facility. Material noncompliance with any one of them, or with any other FDA regulation, could cost the manufacturer its regulatory-compliance defense.

Id. at 1078-79.

Plaintiffs argue that the express preemption discussed in *Bruesewitz* does not apply to their case because *Bruesewitz* involved a claim brought on behalf of an injured minor child. In such situations, Plaintiffs do not disagree that Section 22 would expressly limit some claims for compensation. But, where as here, a plaintiff could not have first filed in Vaccine Court for compensation of individual injuries, Plaintiffs claim Section 22's tort suit limitations are inapplicable. Plaintiffs contend this construction is supported by the fact that Congress did not discuss claims by parents for individual damages in either the Vaccine Act or the Act's legislative history.[8] *See*

[8]To support their interpretation that Section 22 has a narrow reach, Plaintiffs heavily rely on two cases from our Sister Circuits—*Schafer v. American Cyanamid Co.* and *Moss v. Merck & Co.*—which both held that Section 11's exhaustion requirement did not apply to bar parents from filing directly in state court. *See Schafer*, 20 F.3d at 2 ("The question before us in this appeal . . . is whether the Act also bars the family of . . . a person [injured by a vaccine] from bringing a tort suit to obtain compensation for their own, related, injuries, in particular, for loss of companionship or consortium. Assuming that state law permits such suits, we find nothing in the Act that explicitly or implicitly bars them.); *Moss*, 381 F.3d at 505 ("The program delays the filing of only those tort claims for which it first provides an alternate source of compensation."). Plaintiffs cite to numerous

Schafer, 20 F.3d at 6 (discussing parents' claims in context of legislative history).

[6] We disagree with Plaintiffs' cramped interpretation of the Vaccine Act. Given the structure and broad purpose of the Act as a whole, it is most reasonable to apply Section 22 to all design defect and failure to warn claims arising out of a vaccine-related injury or death, not just those that could have first been brought in the Vaccine Court.

First, Part II of the Vaccine Act, in which Sections 11 and 22 appear, is much broader than Plaintiffs would have us construe it. Part II not only establishes the vaccine compensation program and Vaccine Table, but it also outlines the duties of the Secretary of the Department of Health along with the responsibilities and liability of vaccine manufacturers. Moreover, Part II provides any citizen—regardless of whether that person was directly or indirectly harmed by a vaccine-related injury—with a cause of action "against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under [Part II of the Act]." 42 U.S.C. § 300aa-31(a).

The structure of Section 11 further demonstrates that the Act is meant to apply broadly. As subsection (a)(9) in Section 11 explains, Section 11 "applies only to a person who has sustained a vaccine-related injury or death and who is qualified

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district and state court decision for the same proposition as well. *See, e.g.*, *Bertrand v. Aventis Pasteur Labs., Inc.*, 226 F.Supp. 2d 1206, 1214 (D. Ariz. 2002); *Hobart v. Holt*, 194 P.3d 820, 825 (Or. Ct. App. 2008). But critically, none of the cases cited by Plaintiffs discuss Section 22's tort liability limitations. *Cf. Schafer*, 20 F.3d at 5 ([T]he Act *subsection* [in Section 11] that creates the tort action bar says that [the bar] does not apply to this kind of lawsuit.") (emphasis added). Framed another way, these cases interpreted Section 11 to permit parents to file directly in state court. The current case thus picks up where these other cases left off: it considers the claims that may be made against a vaccine manufacturer once a parent is actually in court.

to file a petition[.]" § 300aa-11(a)(9). While this provision makes clear that the subsection's exhaustion requirements apply only to those who personally suffered a vaccine-related injury or death, the provision implies that other sections throughout the Act apply to all types of potential plaintiffs. Section 22, by comparison, applies to any "civil action for damages arising from a vaccine-related injury." § 300aa-22(b). Critically, it does not contain a limiting provision equivalent to the one in Section 11. Thus, Congress's inclusion of the restriction in Section 11—specifically its mention that the bar applies only to that "subsection"— coupled with the lack of such a restriction in Section 22 strongly suggest that Congress did not intend for us to apply the Act's tort suit limitations in the narrow manner urged by Plaintiffs. *See Paul Revere Ins. Group v. United States*, 500 F.3d 957, 962 (9th Cir. 2007) ("It is generally presumed that Congress acts intentionally and purposely when it includes particular language in one section of a statute but omits it in another.") (internal quotation marks and citations omitted).

Section 23, entitled "Trial," confirms this interpretation. In particular, the section sets forth three stages—a liability phase, a compensatory damages phase, and a punitive damages phase—by which a civil action "not barred by section 300aa-11(a)(2) of th[e Vaccine Act] shall be tried." § 300aa-23. By using this language to qualify the types of cases which may proceed to trial, Congress opted for a framework inclusive of all civil actions not otherwise barred by Section 11's exhaustion requirement. Indeed, only applying the trifurcated scheme to lawsuits filed by injured vaccine-recipients, and not to their parents, creates a convoluted trial and liability scenario because the child's case would be subject to the trifurcation, while the parental claim would presumably proceed in a traditional single-phased manner. Under that scenario, the jury would apply the Section 22(b) defenses to the child's claims, but would apply a different set of state legal rules to the parental claims. This interpretation would thus require us to assume that Congress gave greater rights to family mem-

bers of those injured by vaccines than it did to the injured vaccine-recipients themselves. Given that the Act's main purpose is to maintain the nation's vaccine supply while compensating the victims of vaccine-related injuries, this assumption makes no sense.

Moreover, if we were to conclude that the parents of those suffering a vaccine-related injury could bring design defect and failure to warn claims outside of Section 22's limitations, we would be acting contrary to the statute's central purpose of managing vaccine manufacturers' liability because our construction would do little to protect the vaccine manufacturers from suit. *Cf. Bruesewitz*, 131 S. Ct. at 1075 ("If a manufacturer could be held liable for failure to use a different design, the word 'unavoidable' would do no work. A side effect of a vaccine could *always* have been avoidable by use of a differently designed vaccine not containing the harmful element. The language of the provision thus suggests that the *design* of the vaccine is a given, not subject to question in the tort action.").

Finally, in several cases where parent-plaintiffs have filed civil actions for injuries allegedly caused by vaccines and have sought recovery individually and on behalf of child-plaintiffs, courts have applied Section 22 without distinguishing between the claims. Most notably, this scenario played out in *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008), *vacated*, 131 S.Ct. 1567 (2011), *remanded to* 710 S.E.2d 771 (Ga. 2011).

In *Ferrari*, two parents, individually and on behalf of their son, sued various vaccine manufacturers alleging that mercury in a vaccine preservative had caused the child neurological damage. The Ferraris' complaint also alleged several separate state law claims for their own loss of services and emotional distress. In reviewing these claims, the district court held that Section 22 preempted the alleged design defect claims, regardless of whether the parents could have first filed their

suit in Vaccine Court. The Georgia appellate courts reversed. 668 S.E.2d at 237. But then United States Supreme Court vacated the Georgia courts' judgment, making no mention of the difference between the claims of the parents and of the vaccine recipient. *See* 131 S.Ct. at 1567. On remand, the Georgia courts did not readily address this issue either. *See* 710 S.E.2d at 772. In interpreting Section 22, it is thus telling that the *Ferrari* Courts treated the claims of the parents and the claims of the vaccine recipient as equally limited. *See also Sykes*, 484 F. Supp. 2d at 299-301 (Section 22 barred recovery for alleged design defect and failure to warn in action filed by parents "individually and as parents of Wesley Sykes"); *Militrano v. Lederle Labs.*, 810 N.Y.S.2d 506, 506 (N.Y. App. Div. 2006) (Section 22 barred recovery for "the plaintiffs" design defect and failure to warn claims based on immunizations administered to one "infant plaintiff"); *Wright v. Aventis Pasteur, Inc.*, 14 A.3d 850, 852 (Pa. Super. Ct. Jan. 11, 2011) (pursuant to Section 22, no recovery for allegedly defective design or warnings in products liability action filed by plaintiffs "Jacqueline and Howard Wright in their own right, and as parents and natural guardians of Jared Wright, a minor child"), *vacated*, 33 A.3d 1262 (Pa. 2011); *Blackmon*, 328 F. Supp. 2d at 662-66.

[7] We recognize that a parent's loss of a child is an injury distinct from the harm the child himself suffered. But despite Plaintiffs' protests to the contrary, applying Section 22 to their claims does not leave them without a remedy for their injuries. Plaintiffs alleged eight claims plus a claim for punitive damages in their state wrongful death action. Application of Section 22 affects only two of these claims—the strict products liability and negligence claims to the extent that they were based upon allegations of design defect and failure to warn. Therefore six of Plaintiffs' claims remain unaffected by the Act and each of these provide a possible remedy to the injuries that they suffered as a result of Jacob's illness and death. Accordingly, our conclusion is in keeping with the strong presumption that Congress does not, "without com-

ment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *Cf. Shafer*, 20 F.3d at 6.

C

[8] Having concluded that Section 22 generally applies to limit tort liability in a parent's claim for individual injuries, we must determine the extent to which it alters Plaintiffs' lawsuit here. Said another way, we now consider if Plaintiffs' suit is a "civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine," and thus limited by the Act. 42 U.S.C. § 300aa-22(b)(1). We conclude that the Plaintiffs' suit is so limited.

First, the Act defines the term "vaccine-related injury or death" as "an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table . . . ." § 300aa-33(5). Here, the complaint alleges "physical and emotional injuries," and that "plaintiffs were injured in their bodies and their spirit . . . ." Furthermore, recovery under the Nevada wrongful death statute is for an "injury." *See Moyer v. United States*, 593 F. Supp. 145, 146 (D. Nev. 1984) ("The Nevada wrongful death statute, NRS 41.085, designates the only types of injury for which pecuniary damages may be recovered in a wrongful death action."). Second, the injuries are "associated with a vaccination." The complaint alleges that the family suffered injuries "as a direct and proximate result" of Jacob's vaccination. Finally, there is no debate that the M-M-R II vaccine is listed in the Vaccine Injury Table. *See* 42 C.F.R. § 100.3.

III

[9] For these reasons, there is no cause to disturb the district court's application of Section 22 to Plaintiffs' state law products liability claims of design defect and failure to warn. Nor was the district court's grant of summary judgment in

favor of Merck error. During the proceedings below, Merck produced evidence that it had complied with all regulatory requirements related to M-M-R II. But Plaintiffs failed to submit evidence sufficient to show that the vaccine had not been properly prepared or that it had not been accompanied by proper directions and warnings.

Plaintiffs do not challenge on appeal the district court's resolution of the state law claims that the district court held were not preempted by the National Childhood Vaccine Injury Compensation Act.

AFFIRMED.